APR 1 3 2001

Attachment 4
510(k) Summary

K 010956

Category:	Comments
Sponsor:	Boston Scientific Corporation 2710 Orchard Parkway San Jose, CA 95134
Correspondent:	Andrea L. Ruth Associate II, Regulatory Affairs 2710 Orchard Parkway San Jose, CA 95134
Contact Information:	E-mail: rutha@bsci.com Phone: 408.895.3625 Pager: 888.509.6375 Fax: 408.895.2202
Device Common Name	Electrosurgical Probe
Device Proprietary Name	Cobra® Flex™ Family of Surgical Probe
Device Classification	Class II, 21 CFR §878.4400, product code GEI
Predicate Device	Electrosurgical Probe
Predicate Device Manufacturer(s)	BSC/EP Technologies, Inc.
Predicate Device Proprietary Name(s)	Cobra® Surgical Probe
Predicate Device Classification Number	21 CFR §878.4400, product code GEI
Predicate Device Classification(s)	Class II

Date Summary Was Prepared:

April 11, 2001

Description of the Device:

The Boston Scientific Corporation Surgical Probe is a sterile, single use electrosurgical device intended to be used to coagulate soft tissues. The Surgical Probe transmits radiofrequency energy from electrodes which are connected to an Electrosurgical Unit (non-sterile; re-useable) through an Instrument Cable (sterile; re-useable).

Intended Use:

The Probe is intended for use only under direct visual control of the physician during open, general surgical procedures to coagulate soft tissues. The Probe may also be used to coagulate blood and soft tissue to produce hemostasis.

Comparison to Predicate Device:

	Predicate Device	Modified Device
510(k) Reference	K981981	Current Submission
Intended Use	Coagulation of Soft Tissue	Same
Device Description	Electrosurgical Probe	Same
Single Use?	Yes	Same
EO Sterilized?	Yes	Same
Manufacturer	BSC/EP Technologies, Inc.	Same
Device Classification	21 CFR §878.4400, product code GEI	Same

Summary of the Non-clinical Data:

Where appropriate, testing conformed to the requirements of 21 CFR Part 58 (Good Laboratory Practices (GLP). Specifically, non-clinical tests conducted for the Device showed the device met its design-input criteria, and was safe & effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 3 2001

Ms. Andrea L. Ruth
Associate II, Regulatory Affairs
Boston Scientific Corporation
2710 Orchard Parkway
San Jose, California 95134

Re: K010956
Trade/Device Name: Cobra® Flex Family of Surgical Probes
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: March 29, 2001
Received: March 30, 2001

Dear Ms. Ruth:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2
Intended Use Statement

510(k) Number (if known): K010956

Device Name: Cobra® Flex Family of Surgical Probes

Indication for Use:

The intended use remains the same as found in K981981 approved September 3, 1998, and reads as follows:

> The Probe is intended for use only under direct visual control of the physician during open, general surgical procedures to coagulate soft tissues. The Probe may also be used to coagulate blood and soft tissue to produce hemostasis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010956

Prescription Use ✓ OR **Over-the-Counter Use** _____

(Per 21 CFR §801.109)

(Optional Format 1-2-96)